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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/509,734	06/14/2000	SILVIU ITESCU	31856-PCT	2918

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EXAMINER

SAUNDERS, DAVID A

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 05/24/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.



APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
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DATE MAILED:

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 1/17/02

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-19 is/are pending in the application.
Of the above, claim(s) 8-18 is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-7, 19 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☒ The drawing(s) filed on 6/14/00 is/are objected to by the Examiner: Draftsman.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

Art Unit: 1644

The claims pending are 1-19.

The claims under examination are 1-7 and 19.

Applicant's election with traverse of Group I (claims 1-7 and 19) in Paper No. 8 is acknowledged. The traversal is on the ground(s) that the claims of the different Groups bear a common special technical feature and, hence, have unity of invention. This is not found persuasive because irrespective of whether or not there is any common special technical feature, the claims lack unity of invention because applicant's recited kit claims provide no contribution over the prior art.

Use of a labeled anti human IgG antibody and immobilized MHC Class II antigens (components of kit claims 8-9) in an assay for IgG antibody is old (Ten Hoor et al.).

The method of using DTT and complement (components of kit claim 10) in a cytotoxicity assay is old (Ten Hoor et al. or Lazda).

Likewise, the method of using a fluorescent labeled anti-IgG and cells bearing MHC class II antigens (components of kit claim 12) in a flow cytometry assay is known (Lazda).

Since applicant is claiming kits with reagents for known methods an issue of anticipation/obviousness would arise for all Groups pertaining to kits. Applicant has thus not provided a contribution over the prior art, as required by PCT Article 13.1.

The requirement is still deemed proper and is therefore made FINAL.

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

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If applicant desires priority under 35 U.S.C. 119 (e) based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. _____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

If the application is a utility or plant application filed on or after November 29, 2000, any claim for priority must be made during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2) and (a)(5). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) a surcharge under 37 CFR 1.17(t), and (2) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Commissioner may require additional information where there is a question

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whether the delay was unintentional. The petition should be directed to the Office of Petitions, Box DAC, Assistant Commissioner for Patents, Washington, DC 20231.

The disclosure is objected to because of the following informalities: The following misspellings have been noted:

--diffused-- at page 19, line 6.

--HLA- A-- at page 19, line 11.

--system-- at page 21, line 23.

--MHC-- at page 23, line 2.

--anti-II-- at page 24, line 14.

--IgG-- at page 39, line 6.

Appropriate correction is required.

Claims 1-7 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, part (a) "the donor" lacks antecedent basis.

In claim 19, line 4 "a recipient" is unclear. Is this the same as "the recipient" of line 3?

Prior to examination of the claims over the prior art the effective filing date to be accorded to each claim must be determined.

Claims 1-7, that involve a method of predicting graft rejection based upon three variables, are considered to be supported by provisional applications 60/060,992 and 60/090,153.

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Claim 19 only has benefit of the filing date of International application PCT/US98/20887. Neither of the provisional applications provide Example 7, which supports the method of claim 19.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 19 is rejected under 35 U.S.C. 102(a) as being entirely anticipated by Itescu et al.

(Circulation, 98 (8), 786, 1998).

Itescu et al. provide a verbatim disclosure of instant Example 7, which teaches the method of claim 19.

Claim 19 is rejected under 35 U.S.C. 102(b) as being anticipated by Ten Hoor et al.

(Transplantation, 56, 298, 1993).

Ten Hoor et al. show that the presence of IgG anti HLA-DR specific antibodies in serum of a prospective transplant recipient indicates that the recipient is likely to reject an allograft within one year. See abstract, last paragraph. See page 302, col. 2, first full paragraph. See page 303, col. 2, first full paragraph.

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lazda

(Transplantation, 57, 964, 1994).

Lazda provides data suggesting that presence of IgG antibodies directed against HLA-DR antigens increases the risk of allograft rejection. See abstract, last sentence. See page 967, cols. 1-2. While Lazda is not certain that anti-HLA class II (DR) antibodies are the mediators of rejection and thus teaches a need for further studies (page 967, col. 2), it would have been obvious for one to conduct further studies to confirm the findings of Lazda; the motivation to do so is explicitly provided by Lazda. The methods to conduct the studies are routine, and one would have had a reasonable expectation of success in so doing.

Claims 1-7 are allowable over the prior art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, Ph.D., whose telephone number is 308-3976. The examiner can normally be reached on Monday-Thursday from 8:00 a.m. to 5:30 p.m. The examiner can also be reached on alternate Fridays.


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on (703) 308-3973. The fax phone number for the organization where this application or proceeding is assigned is 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

D. Saunders:jmr

May 20, 2002


DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT 182-1644